EXHIBIT 5

Tenn. Code Ann. 63-10-204 (2010)

West's Tennessee Code Annotated
Title 63. Professions of the Healing Arts (Refs & Annos)
Chapter 10. Pharmacy (Refs & Annos)
Part 2. Pharmacy Practice (Refs & Annos)

This section has been updated. Click here for the updated version.

T. C. A. § 63-10-204

§ 63-10-204. Definitions

Effective: August 11, 2010 to April 24, 2013

As used in parts 2-5 of this chapter, unless the context otherwise requires:

(1) “Administer” means the direct application of a drug to a patient or research subject by injection, inhalation, ingestion, topical application or by any other means;

(2) “Board” means the Tennessee board of pharmacy;

(3) “Certification” means a voluntary process by which a practitioner's training, experience and knowledge are identified as meeting or surpassing a standard, defined or approved by the board beyond that required for licensure or registration;

(4) “Compounding” means the preparation, mixing, assembling, packaging or labeling of a drug or device:

(A) As the result of a prescription order or initiative based on the prescriber-patient-pharmacist relationship in the course of professional practice;

(B) In anticipation of prescription orders based on routine, regularly observed prescribing patterns; or

(C) For the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing;

(5) “Continuing education” means planned, organized learning experiences and activities beyond the basic educational or preparatory program. These learning experiences and activities are designed to promote the continuous development of skills, attitudes and knowledge necessary to maintain proficiency, provide quality service or products, be responsive to needs and keep abreast of significant change;

(6) “Continuous quality improvement program” means a system of standards and procedures to identify and evaluate quality-related events and to improve patient care;

(7) “Controlled substance” means a drug, substance or immediate precursor identified, defined or listed in title 39, chapter 17, part 4 and title 53, chapter 11;

(8) “Deliver” or “delivery” means the actual, constructive or attempted transfer from one person to another whether or not there is an agency relationship;

(9) “Device” means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a person duly authorized;

(10) “Dietary supplement” means a product, other than tobacco, intended to supplement the diet that bears or contains one (1) or more of the following ingredients: a vitamin, mineral, herb or other botanical, amino acid, dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract or combination of any of these ingredients and any other products designated as dietary supplements by federal or state law;

(11) “Director” means the director of the health related boards;

(12) “Dispense” means preparing, packaging, compounding or labeling for delivery and actual delivery of a prescription drug, nonprescription drug or device in the course of professional practice to a patient or the patient's agent by or pursuant to the lawful order of a prescriber;

(13) “Distribute” means the delivery of a drug or device, other than by administering or dispensing, to persons other than the patient or the patient's agent;

(14) “Division” means the division of health related boards;

(15) “Doctor of pharmacy” means a person duly licensed by the board to engage in the practice of pharmacy. “Doctor of pharmacy” and “pharmacist” shall be used interchangeably within parts 4-6 of this chapter and, any other provision of Tennessee Code Annotated and in any rule or regulation promulgated by the state of Tennessee and its agencies;

(16) “Drug” means any of the following:

(A) Articles recognized as drugs or drug products in any official compendium or supplement thereto;

(B) Articles, other than food, intended to affect the structure or function of the body of humans or other animals;

(C) Articles, including radioactive substances, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals; or

(D) Articles intended for use as a component of any articles specified in this subdivision (16);

(17) “Executive director” means the executive director of the Tennessee board of pharmacy;

(18) “Label” means any written, printed or graphic matter on the immediate container of a drug or device;

(19) “Labeling” means the process of affixing all labels and other written, printed or graphic matter:

(A) Upon any article or any of its containers or wrappers; or

(B) Accompanying such article;

(20) “Licensure” means the process by which an agency of government grants permission to an individual to engage in a given occupation upon finding that the applicant has attained the minimal degree of competency necessary to ensure that the public health, safety and welfare will be reasonably protected;

(21) “Manufacturer” means any person, except a pharmacist compounding in the normal course of professional practice, engaged in the commercial production, preparation, propagation, conversion or processing of a drug, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis, or both, and includes any packaging or repackaging of a drug or the labeling or relabeling of its container and the promotion and marketing of such drugs or devices;

(22) “Medical order” means a lawful order of a prescriber for a specific patient that may or may not include a prescription order, such orders subject to rules and regulations as may be promulgated from time to time by the respective boards that license the persons who are authorized to prescribe drugs;

(23) “Medication therapy management program” means the distinct service or group of services that optimize therapeutic outcomes for individual patients. Medication therapy management services are independent of but can occur in conjunction with the provision of a medication product;

(24) “Nonprescription device” means a device that may be sold or dispensed without a prescription order and that is labeled and packaged in compliance with applicable state or federal law;

(25) “Nonprescription drug” means a drug that may be sold or dispensed without a prescription and that is labeled and packaged in compliance with applicable state or federal law;

(26) “Patient education” means the communication of information to the patient or caregiver by the pharmacist;

(27) “Patient profile” means a written or electronic record of individual patient information, created in a pharmacy practice, for use by a pharmacist in the provision of pharmacy patient care services, including drug use review and patient counseling requirements. The profile may include, but is not limited to, demographic information, medical history, medication and devices utilized, testing results and pharmacist comments;

(28) “Peer review committee” or “pharmacist review committee” means any committee, board, commission or other entity of any national, state or local professional association or society, including an impaired pharmacist peer review committee, a drug utilization review committee or a committee of any pharmacy benefits management organization, health care provider network, licensed health care institution or any health care organization, system or foundation, the function of which, or one of the functions of which, is to review, evaluate and improve the quality of pharmacy-related services provided by pharmacists or pharmacy auxiliary personnel, to provide intervention, support or rehabilitative referrals or services or to determine that pharmacy-related services rendered by pharmacists or pharmacy auxiliary personnel were professionally indicated or were performed in compliance with applicable quality standards, or that the cost of pharmacy-related services rendered by pharmacists or pharmacy auxiliary personnel was reasonable;

(29) “Person” means any individual, partnership, association, corporation and the state of Tennessee, its departments, agencies and employees, and the political subdivisions of Tennessee and their departments, agencies and employees, except the department of health and local health departments;

(30) “Pharmacist” means an individual health care provider licensed by the state of Tennessee, pursuant to parts 4-6 of this chapter, to practice the profession of pharmacy;

(31) “Pharmacist-in-charge” means the supervisory pharmacist who has the authority and responsibility for compliance with laws and rules pertaining to the practice of pharmacy at the practice site of the pharmacist-in-charge;

(32) “Pharmacy” means a location licensed by this state where drugs are compounded or dispensed under the supervision of a pharmacist, as defined in the rules of the board and where prescription orders are received or processed;

(33) “Pharmacy intern” means an individual enrolled in or a graduate of a recognized school or college of pharmacy under rules established by the board who is serving a period of time of practical experience under the supervision of a pharmacist, as defined in the rules of the board;

(34) “Pharmacy technician” means an individual who is specifically trained and designated to assist pharmacists in the practice of pharmacy;

(35)(A) “Practice of pharmacy” means a patient-oriented health service profession in which pharmacists interact and consult with patients and other health care professionals to enhance patients' wellness, prevent illness and optimize outcomes. The practice involves:

(i) Interpretation, evaluation and implementation of medical orders and prescription orders;

(ii) Responsibility for compounding and dispensing prescription orders, including radioactive substances;

(iii) Participation in drug, dietary supplement and device selection, storage, distribution and administration;

(iv) Drug evaluation, utilization or regimen review;

(v) Maintenance of patient profiles and other pharmacy records;

(vi) Provision of patient education and counseling;

(vii) Drug or drug-related research; and

(viii) Those professional acts, professional decisions or professional services necessary to maintain all areas of a patient's pharmacy-related care;

(B) Nothing in this chapter authorizes a pharmacist to order laboratory tests or prescription drugs except pursuant to a medical order by the attending physician for each patient; provided, that pharmacists are authorized to conduct and assist patients with tests approved for in-home use. Except as described in this section, pharmacists shall not be authorized to order or prescribe legend drugs or order laboratory tests. Pharmacists may convey orders for laboratory tests and prescription orders where required to carry out a medical order when authorized by the attending physician for each patient;

(36) “Prescriber” means an individual authorized by law to prescribe drugs;

(37) “Prescription drug” means a drug that under federal or state law is required to be dispensed only pursuant to a prescription order or is restricted to use by prescribers and that under federal law must be labeled with either the symbol “Rx only” or the statement “Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian”;

(38) “Prescription order” means and includes any order, communicated through written, verbal or electronic means by a physician, certified physician assistant, nurse authorized pursuant to § 63-6-204, who is rendering service under the supervision, control and responsibility of a licensed physician, and who meets the requirements pursuant to § 63-7-207(14), dentist, veterinarian, optometrist authorized pursuant to § 63-8-102(12), or other allied medical practitioner, for any drug, device or treatment. Nothing in this chapter shall prohibit the verbal communication of a direct order for a prescription from a physician to a pharmacist by a registered nurse or physician assistant pursuant to § 63-6-204;

(39) “Provider” or “necessary health care provider” includes a pharmacist who provides health care services within the scope of pharmacy practice;

(40) “Quality assurance program” means a system for identifying problems in patient care that are resolved via administrative, clinical or educational actions to ensure that final products and outcomes meet applicable specifications;

(41) “Quality-related event” means the inappropriate dispensing or administration of a prescribed medication, including, but not limited to:

(A) A variation from the prescriber's medical or prescription order, including, but not limited to:

(i) Dispensing an incorrect drug;

(ii) Dispensing an incorrect drug strength;

(iii) Dispensing an incorrect dosage form;

(iv) Dispensing the drug to the wrong patient; and

(v) Providing inadequate or incorrect packaging, labeling or directions for use; and

(B) Failure to identify, prevent, resolve and manage potential and actual drug and drug-related problems, including, but not limited to:

(i) Over-utilization and under-utilization;

(ii) Therapeutic duplication;

(iii) Drug-age contraindications;

(iv) Drug-allergy contraindications;

(v) Drug-disease contraindications;

(vi) Drug-gender contraindications;

(vii) Drug-drug interactions;

(viii) Incorrect drug dosage;

(ix) Incorrect duration of drug therapy; and

(x) Clinical abuse or misuse;

(42) “Unprofessional conduct” means the conduct of a pharmacist, pharmacy intern or pharmacy technician that is detrimental to patients or to the profession of pharmacy; and

(43) “Wholesaler” means a person whose principal business is buying or otherwise acquiring drugs or devices for resale or distribution to persons other than consumers.

Credits

1996 Pub.Acts, c. 651, § 4, eff. Jan. 1, 1997; 2006 Pub.Acts, c. 768, § 1, eff. May 26, 2006; 2007 Pub.Acts, c. 407, §§ 2, 3, eff. July 1, 2007.

Formerly § 63-10-404

T. C. A. § 63-10-204, TN ST § 63-10-204
Current with laws from the 2016 Second Reg. Sess., eff. through February 1, 2016

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